[1]Providence Arthritis Center, Portland, OR, USA, [2]Ventura County Medical Center, Ventura, CA, USA, [3]Carolina Bone & Joint, Charlotte, NC, USA, [4]i3 Innovus, Eden Prairie, MN, USA, [5]Amgen, Inc., Newbury Park, CA, USA, [6]KForce Clinical Research, Tampa, FL, USA, [7]Amgen, Inc., Thousand Oaks, CA, USA

**OBJECTIVES:** To evaluate effects of dose escalation on clinical outcomes of RA patients initiating TNF-blocker treatments in community practice. **METHODS:** TNF-blocker-naïve adult RA patients initiating etanercept, adalimumab, or infliximab (index) between July 1, 2005 and May 31, 2008 with ≥12 months' enrollment post-index were identified from the Ingenix database. Patients receiving <9 months TNF-blocker treatment or diagnosed with psoriasis, psoriatic arthritis, ankylosing spondylitis, or Crohn's disease were excluded. Rates of dose escalation using 3 different methods were calculated using claims data. Participating physicians provided de-identified charts. Each chart was reviewed by 4–6 clinical rheumatologists to evaluate and agree on overall clinical change from baseline to the visit closest to 1 year post-index (12±3 months). Multivariate models compared change in clinical outcomes and dose escalation rates, controlling for differences among etanercept, adalimumab, and infliximab patients at index. **RESULTS:** Overall, 715 etanercept, 501 adalimumab, and 393 infliximab patients were identified from claims; 141 etanercept, 115 adalimumab, and 104 infliximab patients had evaluable charts. Patient characteristics were similar among the claims and charts. Regardless of dose escalation method used, significantly fewer etanercept-treated patients had dose escalations (1.8%, 5.2%, 6.7%) than patients treated with adalimumab (9.8%, 8.6%, 10.4% respectively) or infliximab (50%, 31%, 34% respectively) ($p<0.05$ for all comparisons). After treatment initiation, 86% of etanercept-treated patients had "much better" or "better" clinical outcomes at 12±3 months, versus 82% of adalimumab patients and 78% of infliximab patients. Multivariate analyses showed significantly fewer dose escalations in etanercept patients ($p<0.05$), with no significant difference in clinical change score between etanercept patients and adalimumab ($p=0.22$) or infliximab ($p=0.07$) patients. **CONCLUSIONS:** This study showed dose escalation in fewer etanercept than adalimumab or infliximab patients, but similar improvements in clinical outcomes for all 3 treatments, indicating that higher dose escalation rates may not be associated with better clinical outcomes.

CO2

## REAL-WORLD COST-EFFECTIVENESS ANALYSIS OF CANCER DRUGS: COMPARATIVE EFFECTIVENESS RESEARCH USING RETROSPECTIVE CANADIAN REGISTRY DATA BEFORE AND AFTER DRUG APPROVAL

Khor S[1], Krahn M[2], Hodgson D[3], Bremner K[4], Luo J[5], Hoch J[1]
[1]Cancer Care Ontario, Toronto, ON, Canada, [2]Toronto Health Economics and Technology Assessment (THETA) Collaborative, Toronto, ON, Canada, [3]Princess Margaret Hospital, Toronto, ON, Canada, [4]University Health Network, Toronto, ON, Canada, [5]The Institute for Clinical Evaluative Sciences, Toronto, ON, Canada

**OBJECTIVES:** Using linked administrative databases from Ontario, our study examined the "real world" cost, effectiveness and cost-effectiveness of Rituximab in diffuse-large-B-cell lymphoma. **METHODS:** Patients were defined as those who had a diagnosis of diffuse-large-B-cell lymphoma according to ICD-O histology classification between January 1997 and December 2007 and received either CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or R-CHOP (CHOP plus Rituximab) as first line treatment. We used a historical cohort design to compare the overall survival, toxicity profiles, direct costs, and cost-effectiveness of CHOP before Rituximab was approved (pre-era CHOP) with R-CHOP after Rituximab approval (post-era RCHOP). R-CHOP and CHOP patients were hard-matched on age, and then subsequently matched on propensity scores by use of a 1:1 matching algorithm. Propensity scores were calculated from demographic and clinical history information. We estimated resource use and direct medical costs using the linked administrative data. To analyze censored cost data, we employed and compared different methods, including the simple non-adjusted average, the Kaplan-Meier sample average estimator, inverse probability weighting estimator, Pfeifer and Bang's estimator (2005) and Basu's two-part estimator (2010). **RESULTS:** A total of 1131 matched pairs of patients were evaluated. 3-year overall survival was significantly improved in the post-era RCHOP group compared to pre-era CHOP (69% [95%CI 66-71] vs 59% [95%CI 56-62]; Klein test $p<0.001$). Groups did not differ in the frequency of adverse events, but 3-year direct cost was significantly higher in the post-era RCHOP group. The incremental cost-effectiveness ratio varied depending on the method employed. **CONCLUSIONS:** This study illustrated how different methods can be applied to observational data to estimate costs and cost-effectiveness. The results from this study can be compared to those from clinical trials and economic models. This will help drug decision-makers calibrate healthcare policies while helping researchers evaluate assumptions made and methods used in economic models.

CO3

## PROJECT LIBRA: A NEW ANALYTIC TOOL FOR COMPARATIVE EFFECTIVENESS ANALYSES OF MULTIPAYER CLAIMS DATABASES

Mark T[1], Pepitone A[2], Hatzmann M[1], Navathe A[3], Goodrich K[3], Chang S[1]
[1]Thomson Reuters, Washington, DC, USA, [2]Thomson Reuters, Santa Barbara, CA, USA, [3]Assistant Secretary for Planning and Evaluation, Washington, DC, USA

**OBJECTIVES:** The project aimed to develop a secure, interactive tool to enable researchers to perform comparative effectiveness studies and other types of research on a multipayer claims database with reduced need for complicated programming. **METHODS:** A common data model, through which multiple data sources are standardized and linked via common data structures and vocabularies, was established. It was used to format five administrative databases: the Medicare Chronic Condition Warehouse, the Thomson Reuters MarketScan® Medicaid Multistate, Medicare Supplemental, and Commercial databases, and the Healthcare Cost and Utilization Project National Inpatient Sample database. A web-based User-Interface was developed that captures the logic typically required by CER methods and capitalizes on the longitudinality of administrative data. Tools were developed to allow users to search taxonomies to select particular drugs, diagnoses, or procedures by typing in substrings of the numeric codes or textual descriptions. The tool allows researchers to apply enrollment and demographic constraints and create variables. CER studies were conducted including a comparison of atrial fibrillation treatment with rate or rhythm control medications. **RESULTS:** The tool allowed users to quickly define a study sample. Flow diagrams graphically illustrated the attrition of the sample size and visualization of treatment and outcomes. Embedded SAS procedures enabled reporting and analysis of comparison populations. The analyses revealed a higher rate of coronary artery disease and heart failure prior to drug initiation among the amiodorone versus the calcium channel blocker population and a higher rate of post-drug initiation acquired hypothyroidism, and pulmonary disease among the amiodorone versus the calcium channel blocker population. **CONCLUSIONS:** New data designs and software analytic tools may allow claims databases to be more efficiently leveraged. The tool developed for this project has the following advantages: 1) allows for a substantial portion of the research exploration, hypothesis generation; and statistical analysis to be performed in real-time using a web-based interface; 2) improves the speed of research; and 3) allows access to a multipayer database.

CO4

## POTENTIAL COST SAVINGS FROM COMPARATIVE EFFECTIVENESS RESEARCH: LESSONS FROM COURAGE STUDY

Bonakdar tehrani A, Howard D
Emory University, Atlanta, GA, USA

**OBJECTIVES:** During the debate over health reform, comparative effectiveness research was touted as a relatively painless approach to reducing costs. A comparative effectiveness study of two treatments will find either that the costlier treatment is more effective or is not more effective than a less expensive alternative. Studies that report negative results have the potential to reduce costs, but only if findings affect clinical practice. One concern is that the same factors that promote rapid adoption of new therapies in the U.S. may retard the abandonment of existing technologies found to be ineffective. **METHODS:** The COURAGE trial found that optimal medical therapy is as effective as percutaneous coronary intervention (PCI) for patients with stable angina. PCI refers to stenting and angioplasty. The trial was published and widely publicized in early 2007. We evaluate trends in PCI volume pre- and post-COURAGE by indication using 1) 100% samples of outpatient and inpatient discharge data for California, Florida, New Jersey, and Maryland, 2) a 100% sample of discharge data for Veteran's Administration hospitals and 3) data from a proprietary cardiac catheterization laboratory registry at 15 hospitals. **RESULTS:** Between the fourth quarter of 2006 and the fourth quarter of 2007, PCI volume in California, Florida, New Jersey, and Maryland among patients without serious coronary disease declined from approximately 17,000 to 13,000 procedures (an 18% decline). There was only a 5% decline among patients with unstable angina, who were not included in COURAGE. We found similar patterns in the other datasets. **CONCLUSIONS:** Publication of the COURAGE trial had an impact on PCI volume. Many patients with stable angina continue to receive PCI. The results are consistent with the view that as long as the health system is configured around procedural-based medicine, the impact of trials which find that medical therapy is as effective as invasive procedures will be modest.

# PODIUM SESSION I: EFFECTS OF DRUG MANAGEMENT PROGRAMS ON PATIENTS

DM1

## IMPACT OF A PHARMACY REFILL MANAGEMENT SYSTEM ON OUTCOMES IN END STAGE RENAL DISEASE (ESRD) PATIENTS

Rubin JL[1], Wilson SM[1], Golomb J[2]
[1]DaVita Clinical Research, Minneapolis, MN, USA, [2]DaVita Rx, San Bruno, CA, USA

**OBJECTIVES:** In dialysis patients, bone and mineral (phosphorous, calcium) and regulatory hormones (parathyroid hormone (PTH)) become dysregulated, increasing risk of fractures, cardiac events and death. First line treatment is a low phosphorus diet and prescription phosphate binders. We examined the impact of a refill management system (RMS) - which helps patients proactively manage their refills using predictive algorithms and refill reminders for prescriptions - on serum phosphorus, calcium and PTH in patients prescribed phosphate binder monotherapy. **METHODS:** Data from a large dialysis organization were used to identify dialysis patients prescribed monotherapy phosphate binder between 1/1/2008-9/30/2010 with at least 6 months of follow-up. Patients enrolled in the RMS were 1:1 propensity score matched to patients not enrolled utilizing age, race, gender, dialysis vintage, body mass index, baseline laboratory values (albumin, calcium, Kt/V, phosphorus, PTH, normalized protein catabolic rate), Charlson comorbidity score, and other comorbid conditions commonly associated with ESRD. The matched cohorts were compared on the percent meeting guideline ranges for phosphorus (3.5-5.5 mg/dL), corrected calcium (8.4-9.5 mg/dL) and PTH (150-600 pg/mL). Values were assessed over the 6-months following the first phosphate binder prescription. Differences between groups were tested using chi-square for proportions. **RESULTS:** 3,247 RMS patients met the inclusion criteria and were matched 1:1 to a cohort of non-RMS patients. There were no significant differences between the groups on any baseline variables. Patients enrolled in the RMS were more likely to be in target range over the 6 month period on all 3 measures: phosphorus (58.0% vs 55.1%); corrected calcium (74.3% vs. 69.1%) and PTH (80.5% vs. 77.2%), compared to propensity matched controls. All differences were significant at the $p<0.05$ level. **CONCLUSIONS:** Results indicate that participation in a pharmacy RMS is associated better laboratory outcomes for dialysis patients.